RFA 05-01: CIRM TRAINING PROGRAM

OBJECTIVE OF THIS REQUEST FOR APPLICATIONS - RFA 05-01

The goal of the California Institute for Regenerative Medicine (CIRM) is to use stem cell and related research to develop new therapies for disease. The Institute thus encourages training in stem cell research that fosters an active interest in, and knowledge of, human diseases, as well as a thorough and critical understanding of fundamental biology.

KEY FEATURES OF THE CIRM TRAINING PROGRAM

To accomplish its training goals, CIRM will offer grants to California public colleges and universities and non-profit academic and research institutions in California to foster training at the level of pre-doctoral students, post-doctoral students and clinical fellows. Not every institution will be able to offer training at all levels; moreover, the number of faculty, students and fellows engaged in stem cell research differs widely among institutions. Training grants are thus offered at several levels of support to accommodate the capabilities of different institutions.

All training programs must offer one or more classes in stem cell biology and its application to health and disease, and a required course in the social, legal and ethical implications of stem cell research, along with other training activities. Moreover, all programs must offer opportunities for laboratory work under the direction of a mentor in stem cell biology or clinical training that is closely related to stem cell research. Stem cell research is interpreted broadly to include research related to adult and embryonic stem cells in or from all relevant organisms. Because the goal of CIRM is to utilize stem cells to develop new therapies for

disease, the Institute encourages interactions among basic and clinical scientists that may speed the translation of basic findings to clinical treatment.

An important aim of the overall training program is to provide training for a wide variety of trainees from scientifically diverse backgrounds, including relevant fields of biology (developmental biology, cell biology, neurobiology, molecular biology, etc.), clinical training programs (medicine, surgery, neurology, cardiology, psychiatry, etc.), bioengineering (tissue engineering, biomedical imaging, etc), as well as ethics and law, where appropriate. Although stipends are offered to support a limited number of trainees, the program is intended to be a resource for a much larger number of students, fellows, and interested faculty. CIRM specifically wishes to promote interactions among trainees from different fields, especially between those trained in basic science/engineering and clinical medicine. To achieve this goal, each institution is expected to offer a single, integrated program of training that is appropriate for the educational level of its trainees and the areas of expertise of its faculty.

Because of the diversity of the California population, CIRM is particularly interested in training a diverse pool of investigators. We encourage institutions to make special efforts, consistent with the law, to recruit and retain individuals from many backgrounds, including under-represented minorities, as trainees and as mentors.

All research conducted under the auspices of this grant will be guided by the CIRM grants and research standards policies, which will be issued at a later date.

TYPES OF TRAINING PROGRAMS

All training grants will be funded for up to three years. Recognizing that different institutions have different capabilities and areas of strength, grants will be awarded for three types of programs.

Type I - Comprehensive training programs: Comprehensive programs will offer training at all three educational levels: pre-doctoral, post-doctoral and clinical. Each institutional grant may support up to 16 trainees, with a total (direct and indirect) cost/budget of up to $1.25 M per year. The apportionment of trainees among the different levels of education is to be determined by the institution. Type I grants are most appropriate for medical schools or universities with medical

schools that have large research programs in stem cell research and well-established programs of graduate training.

Type II - Intermediate training programs: Intermediate programs will offer training at two of the three levels of education (e.g. pre-doctoral and post-doctoral; post-doctoral and clinical; or pre-doctoral and clinical). Each award may support up to 10 trainees, with a total (direct and indirect costs) budget of up to $800,000 per year. Type II grants are suitable for institutions with medical schools that may have less extensive stem cell research programs, for institutions without medical schools, but with strong pre-doctoral and post-doctoral training opportunities, or for research institutes or hospitals conducting extensive stem cell research.

Type III - Specialized training programs: Specialized programs will offer training at one or two levels of education. Each grant may support up to 6 trainees, with a total (direct and indirect costs) budget of no more than $500,000 per year. These grants may be suitable for smaller institutions with relatively small stem cell research programs.

COMPONENTS OF TRAINING PROGRAMS

1. Trainees: Each training program will choose the apportionment of trainees at different levels of scientific/clinical education that is suitable for its capabilities, including the pool of potential trainees and the expertise and the availability of mentors. Each trainee will be designated as a **CIRM Scholar**.
    a. Pre-doctoral students will generally be enrolled in doctoral degree (Ph.D.) programs related to stem cell research. Pre-doctoral students in a professional school in a medically-related field such as medicine, dentistry and veterinary medicine may also be included at the discretion of the institution. Students may be appointed to the training grant at any point in their doctoral programs.
    b. Post-doctoral fellows will have received a Ph.D. or a professional doctorate in a medically-related field and will be pursuing laboratory or clinical research with a mentor in some aspect of stem cell biology or medicine.

c. Clinical fellows will have received a professional doctorate in a medically-related field and will pursue stem cell research training either in a laboratory or in the clinic. Clinical fellows will normally be at the residency or immediate post-residency level of training.

d. Trainees are not required to be California residents or US citizens. The training grant program is designed to encourage trainees to complete their education and serve as stem cell researchers in California.

e. There is no trainee payback requirement.

2. Mentors: Each trainee appointed to the training grant will have an assigned mentor who is an experienced clinical or basic scientist in areas related to stem cell biology including diseases or conditions that could potentially benefit from stem cell research. Mentors are expected to provide guidance and laboratory or clinical research opportunities to their individual trainees and to participate actively in the CIRM Training Program. They will provide annual assessments of their trainees' progress and plans for the next phase of their training. These individual assessments will become part of the annual training program report to CIRM. Mentors should be chosen for both their scientific expertise and their mentoring experience and quality.

3. Program Director: Each program will have a senior scientist who leads and coordinates the institutional CIRM Training Program. This individual will have primary responsibility for all programmatic and administrative aspects of the training grant, including adherence to budgetary, policy, and reporting requirements. The Program Director will prepare an annual report that describes appointments of trainees and mentors, description of their individual progress and plans for the next budget period, academic and ancillary programs conducted under the aegis of the training grant, actual distribution of budget expenditures, and explanation of any major changes in the program during the past year or proposed for the next year.

4. An Integrated Program of Training

a. Overall Program:

Each institution is expected to have a single integrated training program for all of its stem cell trainees. Only a single training grant will be awarded to each institution, regardless of the number of schools, departments or graduate programs that participate. For the purposes of this RFA, each campus of the University of California is regarded as a separate institution. If training at the pre-doctoral level is offered, the institution must have relevant graduate programs of high quality from which pre-doctoral trainees may be drawn. Mentors for pre-doctoral training are expected to be members of these programs. Some institutions may not have pre-doctoral training programs, but may offer post-doctoral and/or clinical training. Institutions may thus differ in the components that are offered, but within a single institution, all components of training must be integrated into a single program.

b. Courses:

All institutions are expected to offer, or to have available through a nearby institution, one or more courses in stem cell biology and its application to human disease. Courses for basic scientists that provide exposure to clinical aspects of disease are especially encouraged. The courses that are offered may be new courses or adaptations of pre-existing courses. In addition, each institution must offer a mandatory course for all trainees in the ethical, legal and social implications of stem cell research. Institutions may cooperate with other, nearby institutions to share resources.

c. Program Activities:

The training program should include activities that keep trainees apprised of recent developments in the stem cell field and that foster interaction among them, such as journal clubs, seminar series or in-house meetings to discuss new data from on-going research. These activities may already be part of existing programs, but the novel elements need to be clearly identified as components of the CIRM training program and must serve the needs of the CIRM trainees.

d. Institutional Collaborations:

Each training grant will be awarded to a single institution for training at that institution. Several institutions may collaborate, however, to offer a more comprehensive training

program for all their trainees than any single institution is able to provide. How this will occur should be spelled out in the application (see below).

e. Clinical Fellows:

Clinical fellows may participate in laboratory research or patient-based clinical research but must participate in all other components of the training program. The ways in which the program will direct and enhance their training should be described clearly.

f. Laboratory Course:

CIRM also wishes to support basic training in laboratory techniques for stem cell research. Because of the significant expense involved, however, this will be the subject of a future initiative.

ELIGIBLE COSTS

1. Trainee Expenses
   a. Stipends
      i. Pre-doctoral: $25,000/year
      ii. Post-doctoral: $36,000-$51,000, depending on seniority level (according to NIH definitions and guidelines)
      iii. Clinical fellows: $65,000-$75,000, depending on years of prior training
   b. Trainee Tuition and Fees
      i. Health insurance
      ii. Institutional student fees
      iii. Tuition subsidy for pre-doctoral students (use NIH formula for calculation)
   c. Research related funds: laboratory supplies, travel, books
      i. Pre-doctoral students: $5,000/yr
      ii. Post-doctoral and clinical fellows: $10,000/yr

2. Program Administration (linked to number of trainees)
   a. $3500 per trainee/yr

b. May be used for administrative support salaries, seminar speakers, outside speakers for courses, audio-visual equipment or supplies, costs of developing or delivering new courses. Up to 5% may be used for salary support for the Program Director.

3. Indirect Costs:

a. Indirect costs will be given at a level of 10% of the total direct costs.

FUNDS AVAILABLE

CIRM intends to commit approximately $45 Million over a 3 year period for this program. The Institute anticipates that approximately 6 grants of each type (Type I, II or III) will be funded. There may be other opportunities in the future for funding of stem cell training programs.

APPLICATION PROCEDURE

Letter of Intent

All institutions planning to apply for a CIRM Training Grant must notify CIRM in a one page letter of intent by **June 1, 2005**. The letter should describe the type of training grant (Type I, II, III), and the educational levels of trainees receiving the training (pre-doctoral, post-doctoral and clinical). If collaboration with other institutions is planned, this should also be described. Letters of intent are non-binding, but applications will not be accepted from institutions that have not provided such a letter. Letters of intent can be sent as an email to **TRAINING@cirm.ca.gov** accompanied by a signed, hard copy to:

Training Grant Application
California Institute for Regenerative Medicine
P.O. Box 99740
Emeryville, CA 94662-9740

Full Application Instructions

A. Abstract:

State concisely (within the space provided) the proposed program of training including the level(s) of training, the numbers of trainees, the nature and scope of courses and ancillary activities, and the range of research opportunities available in the program. Include a description of multidisciplinary and/or collaborative activities if such will be offered.

B. Overall Description of the Program (no more than 3 pages):

a. Describe the specific focus and purpose of the training program, including level(s) of proposed trainees (Type I, II, or III).

b. Describe the formal training to be offered as part of the program.

i. Required courses: describe briefly the material to be covered in each course; state whether each course is to be developed specifically for this program; if it is a modification of an existing course, specify how it is modified specifically to serve the mission of this program.

ii. Optional courses: describe the content of each course offered, whether it is an extension or modification of a pre-existing course, or whether it is designed specifically for this program. If a pre-existing course is modified for the program, describe how the modifications fit the goals of the CIRM Training Program.

c. Describe related activities that are integral to the stem cell training program, such as seminar series relevant to stem cell research, scientific retreats, journal clubs, field trips to other laboratories conducting related research, and group meetings of program participants. Indicate how pre-existing activities are adapted to the training program.

d. Describe plans for the scientific and administrative leadership and oversight of the program.

e. Describe any plans to collaborate with programs at other institutions to provide a more effective overall training program; include a letter of agreement from each collaborating institution describing the nature of the collaboration.

f. Describe the institutional support for this program.

Use no more than 4 pages for Sections C, D and E combined.

C. Trainees:

1. Selection of trainees

   i. Pre-doctoral students:

      - Describe the size (number of training faculty and students) and scientific scope of pre-doctoral programs from which students might be drawn for the CIRM Training Program.
      - Provide indications of the quality of these existing programs: years in existence, NIH Training Grant history, average GPA and GRE of entering students, and other indications of the quality of the program such as prestigious fellowships awarded to recent graduates.

   ii. Post-doctoral and clinical fellows: Describe your institution's or department's selection criteria for recruiting postdoctoral and clinical fellows.

2. Selection process: How will trainees at each level be selected for appointment to this training grant? Will new appointees be selected each year or will trainees continue for several years in the program? (Either is acceptable.) Describe efforts that will be made to ensure a diverse group of trainees and to encourage and train under-represented minorities.

D. Mentoring

a. Describe how trainees at each level of training will be mentored.
b. Explain how the quality of mentoring received by each trainee will be assessed.
c. Describe the expectations for the types of mentors that are being proposed for this training program (e.g., laboratory in which trainee would work; faculty available to provide additional mentoring).

E. Assessment of Progress

a. Trainees: Describe how progress will be assessed for trainees at each level. Explain how the CIRM Training Program is designed to guide and, where necessary modify the training plans of individual trainees.
b. Overall program: Clarify how the effectiveness of the overall training program will be evaluated.

F. Key Personnel (pages as needed)

For the Program Director and for each proposed mentor, provide a 2-page biographical sketch that highlights the individuals' stem cell-related activities, and include an indication of the number of previous pre- and post-doctoral and clinical students trained by each of them.

G. Institutional Research Resources for Stem Cell Research (no more than 1 page)

Provide a 1-page description of specialized facilities, equipment and other resources to be used for the proposed stem cell training program. Indicate performance sites and describe capabilities, availability, and proximity to the program.

REVIEW AND AWARD PROCESS

CIRM Training Grant applications will be reviewed by the Scientific and Medical Research Funding Working Group of CIRM (also referred to as the Grants Review Working Group). This Working Group consists of fifteen basic and clinical scientists from institutions outside California, seven patient advocates who are members of the Independent Citizen's Oversight Committee (ICOC), and the Chair of the ICOC. The ICOC was established by the California Research and Cures Act (Proposition 71) to oversee CIRM.

The fifteen scientists on the Working Group will review the applications and rate them according to scientific and training merit. Among the qualities to be considered are: overall quality of the planned training program, qualifications of the program leadership, research and training strength of the mentors, the quality of the existing training programs and the strength of stem cell research at the institution. Each of the three types of training awards (Type I, II and

III) will be ranked separately. The full Grants Review Working Group will then choose those awards to be considered by the ICOC.

SUBMITTING AN APPLICATION

All applications must be received by **July 1, 2005**. Applications must be prepared using the CIRM Training Grant Application Form which will be available on the CIRM website as of June 1, 2005**.** Send a PDF file of the full application to: **TRAINING@cirm.ca.gov.** In addition, submit a signed original of the application, and the full application on a CD in one package to:

Training Grant Application
California Institute for Regenerative Medicine
P.O. Box 99740
Emeryville, CA 94662-9740

RECEIPT AND ANTICIPATED REVIEW AND START DATES

Receipt of Letters of Intent:	June 1, 2005
Receipt of full application:	July 1, 2005
Review of applications:	August, 2005
Review by ICOC:	September, 2005
Announcement of awards:	September, 2005
Earliest funding of awards:	October, 2005

Contact Information

Arlene Y. Chiu, Ph.D.
Director of Scientific Program and Review Activities
California Institute for Regenerative Medicine
P.O. Box 99740
Emeryville, CA 94662-9740
Email: achiu@cirm.ca.gov

Phone: (510) 450-2418

FAX: (510) 450-2434

OTHER REQUIREMENTS

Stem Cell Research Guidelines:

CIRM will shortly be adopting standards for human embryonic stem cell research. Recipients of CIRM support will be advised of the new standards when they are adopted. All research conducted under this award will be expected to comply with the stated standards.

Care and Use of Animals in Research:

Recipients of CIRM support for research involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf) and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable.

Human Subjects Protection:

Federal regulations require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).